

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

OUTSOURCING FACILITIES
ASSOCIATION and NORTH AMERICAN
CUSTOM LABORATORIES, LLC d/b/a
FARMAKEIO CUSTOM COMPOUNDING,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION and DR. MARTIN A.
MAKARY,

Defendants, and

ELI LILLY AND COMPANY,

Intervenor-Defendant.

CASE NO. 4:24-cv-953-P

ELI LILLY AND COMPANY'S MOTION FOR SUMMARY JUDGMENT

Intervenor-Defendant Eli Lilly and Company ("Lilly") files this Motion for Summary Judgment (the "Motion"), pursuant to Rule 56 of the Federal Rules of Civil Procedure, and would respectfully show the Court as follows:

SUMMARY

By this Motion, Lilly moves the Court for summary judgment on all six causes of action in Plaintiffs' Amended Complaint. [ECF No. 68 at 17–24]. Specifically, Defendants are entitled to judgment on the following claims:

1. Count I ("Agency Rulemaking Without Requisite Notice, Comment, and Explained Decision");
2. Count II ("Lack of Reasoned Decisionmaking by Omission of Rationale Sufficient to Explain Final Agency Action");

3. Count III (“Lack of Reasoned Decisionmaking by Arbitrary and Facially Contradictory Findings That Refute or Undermine the Basis of Final Agency Action”);
4. Count IV (“Arbitrary and Capricious Determination That Tirzepatide Shortage Ended”);
5. Count V (“Unlawful Interpretation and Application of Drug Shortage Statute”); and
6. Count VI (“Unlawful Failure to Publish Decision in the Federal Register”).

For the reasons detailed in Lilly’s Brief filed concurrently with this Motion and incorporated herein by reference, Lilly respectfully requests that the Court grant its Motion and enter summary judgment under Rule 56 in Defendants’ favor as to all of Plaintiffs’ claims.

SUPPORTING APPENDIX

As required by Local Civil Rule 56.6, Lilly is filing a sequentially numbered Appendix with supporting evidence. Lilly’s supporting Brief will cite to specific pages in the Appendix as “Lilly App. ____.”

Dated: April 2, 2025

Respectfully submitted,

/s/ James F. Hurst

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CERTIFICATE OF SERVICE

I certify that on April 2, 2025, a copy of this document was served electronically in accordance with the Federal Rules of Civil Procedure.

/s/ James F. Hurst
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